UNITED
NATIONS

E

Economic and Social
Council

Distr.
GENERAL

E/CN.4/2001/93
28 December 2000

ENGLISH
Original: ENGLISH

COMMISSION ON HUMAN RIGHTS
Fifty-seventh session
Item 17 (d) of the provisional agenda

PROMOTION AND PROTECTION OF HUMAN RIGHTS: SCIENCE AND ENVIRONMENT

Human rights and bioethics

Report of the Secretary-General

I. INTRODUCTION

1. At its fifty-fifth session, the Commission on Human Rights, in its resolution 1999/63, took note with satisfaction of the report of the Secretary-General on human rights and bioethics (E/CN.4/1999/90) and invited the United Nations Educational, Scientific and Cultural Organization, the World Health Organization, the Office of the High Commissioner for Human Rights and the other United Nations bodies and specialized agencies concerned to report to the Secretary-General on the activities conducted in their respective areas to ensure that the principles set forth in the Universal Declaration on the Human Genome and Human Rights are taken into account. It invited the Secretary-General to draw up proposals on the basis of these contributions concerning ways of ensuring proper coordination of bioethics activities throughout the United Nations system.

2. The Commission also invited Governments to consider establishing independent, multidisciplinary and pluralist committees of ethics to assess, notably in conjunction with the International Bioethics Committee of the United Nations Educational, Scientific and Cultural Organization, the ethical, social and human questions raised by the biomedical research undergone by human beings and, in particular, research relating to the human genome and its applications and invited them to inform the Secretary-General of the establishment of such bodies, with a view to promoting exchanges of experience between such institutions.

3. The Commission requested the Secretary-General to submit a report based on these contributions for consideration by the Commission at its fifty-seventh session. The present report is submitted to the Commission in accordance with the requests contained in resolution 1999/63.

4. By communications dated 27 September 1999, the Secretary-General invited Member States and the relevant United Nations bodies and specialized agencies to submit their contributions pursuant to that resolution to the Office of the High Commissioner for Human Rights by 30 March 2000. The Secretary-General sent a reminder note to States and the relevant United Nations bodies and specialized agencies on 9 August 2000.

5. By 20 November 2000, replies had been received from the Governments of Brazil, Croatia, Cyprus, Denmark, the Holy See, Jordan, Pakistan, Peru, Qatar, the United Kingdom of Great Britain and Northern Ireland and the United States of America. No replies were received from the United Nations bodies and specialized agencies concerned. It was accordingly not possible to draw up proposals based on contributions by United Nations agencies on ways of ensuring proper coordination of bioethics activities throughout the United Nations system.

II. REPLIES

6. The Government of Brazil indicated that recent efforts have been made in Brazil to encourage responsible decision-making in the field of science. It noted that rules of ethics in the field of health research were approved by the National Health Council in 1988 and were then used for the accreditation of research centres. The Government noted, however, that by 1995 scientific developments had created a need to review these rules. To this end, a multidisciplinary group including professionals in the fields of philosophy, theology, law and biomedicine as well as representatives of the users of the public health system, women's groups, the pharmaceutical industry and governmental services, was designated to consult with members of Brazilian society and to create proposals on issues regarding ethics and science. The consultative process, which included a review of legislation of several countries and a survey of international organizations, resulted in the approval of the Brazilian Guidelines and Regulating Norms for Research Involving Human Subjects (resolution NR 196/96) by the National Health Council in October 1996. The resolution established the National Committee for Ethics in Research (CONEP) which is currently working to issue guidelines in areas such as human genetics, assisted reproduction and international cooperation. The Government noted that the challenge now lies in the implementation of this new culture of ethics in Brazilian institutions, a challenge which will be facilitated by the work of the nearly 260 multidisciplinary Committees for Ethics in Research. Resolution 196/96 also outlines the responsibilities and obligations of all parties involved in the research and sets out research guidelines. All research projects must be approved by an institutional committee. Projects in areas of specialization, such as those involving assisted reproduction, genetics, indigenous groups and international cooperation, must be submitted to the National Committee for approval. The National Committee has published research norms in areas involving new drugs, vaccines and diagnostic tests, and research on international cooperation. The Ministry of Health has established an office to coordinate the national system of Committees for Ethics in Research, including the development of training programmes and management support.

7. The Government of Croatia reported that the Croatian Medical Association had established a Commission for Ethics and Deontology to monitor the implementation of the rules of medical ethics and deontology and to take appropriate measures in case of their violation. According to the Croatian Health Care Act, all health-care institutions must have an ethical commission to ensure that their operations comply with the principles of medical ethics and deontology. Article 52 of the Act specifies the responsibilities of the commissions as follows: implementing the ethical principles of the health-care profession in the operation of health-care institutions, monitoring the testing of medicines and medical products, approving scientific research in health-care institutions, supervising the taking of deceased persons after an autopsy for scientific and educational purposes, and dealing with other ethical issues in the operation of health-care institutions. By its decree of 11 May 2000, the Government also established the Bioethical Commission for Monitoring Genetically Modified Organisms in order to prepare proposals, opinions and expert explanations about genetically modified organisms.

8. The Government of Cyprus reported the establishment of bioethics committees in the framework of the Pancyprian Medical Association, the Bank of Cyprus Oncology Centre and the Cyprus Institute of Neurology of Genetics. The Pancyprian Medical Association is responsible for the approval of proposals for medical research. In April 2000 it recommended the establishment of a Bioethics Committee responsible for considering proposals for biomedical research and making recommendations to physicians according to the Helsinki Declaration. The Bioethics Committee is to have particular regard for the conduct of research that may affect the physical and mental condition of the patient, the environment and animals. The Bank of Cyprus Oncology Centre established a Medical Research Ethics Committee to consider applications for clinical trials to be carried out at the Centre in accordance with the Good Clinical Practice Guidelines. The Committee, which was established based on the Guidelines of the Royal College of Physicians of London and the code currently used by the Greek National Ethics Committee, operates according to the principles set out in the Helsinki Declaration. All clinical trials at the Centre must be approved by the European Medicines Control Agency (MCA) as there is no MCA equivalent in Cyprus. The Department of Pharmaceutical Services of the Ministry of Health in Cyprus is informed whenever a study is approved and takes place at the Centre. The Government indicated that insurance is provided for those research patients enrolled in drug company-funded clinical trials, but noted that the situation with regard to insurance for other patients is unclear. It noted the need for formal training and guidance in the establishment of ethics committees. The Government reported the establishment by the Scientific Council of the Ethics Committee of the Cyprus Institute of Neurology and Genetics (CING) in 1994, the first of its kind in Cyprus. The aim of the Committee is to review research projects carried out at CING involving human subjects and/or samples, which now require the Committee's approval. The Government gave details on the current composition of the Committee and noted the adoption by the Committee of the Helsinki Declaration and the European Union's guidelines on good clinical practice.

9. The Government of Denmark described the role and composition of the Danish Council of Ethics, established in 1988, which consists of 17 members appointed by the Minister for Health. The Minister has the right to nominate eight members independently, while the

remaining nine members are nominated by a special parliamentary committee. The Government noted that part of the Council's functions is to inform and encourage debate in the public sector. The Council also has an advisory function with the health authorities on, for example, general ethical issues concerning the use of new methods of treatment, medical technology and the setting of priorities. In order to fulfil these functions, the Council holds conferences, attends lectures, publishes literature and prepares educational material. The Council has an advisory function with regard to ethical questions regarding the recording, forwarding and use of information on hereditary diseases. According to the legislation, the Council must make recommendations to the Ministry of Health on the establishment of rules and provisions in statutes on fertilized eggs, embryos, genetic experiments on sex cells, new techniques for pre-diagnosis and other issues. The Government noted that ethical research committees had been established by the Ministry of Research to ensure the protection of research subjects and to guide the judgement of biomedical research projects.

10. The Holy See reported that a Working Group on Bioethics was set up in 1994 within the State Secretariat. The Working Group is composed of experts in the fields of medicine, genetics, ethics and law. It plays an advisory role, in particular with regard to initiatives undertaken at the international level.

11. The University of Jordan reported that members of the Faculty of Science and the Faculty of Medicine had expressed an interest in joining a committee of ethics to assess the ethical, social and human questions raised by biomedical research on human beings.

12. The Government of Mexico reported that it had established a National Commission for Bioethics eight years ago and that it has promoted several bioethics committees, as well as committees on clinical ethics, in all institutions and hospitals within the health-care system. The Government noted its participation in the Third Global Summit on National Bioethics Commissions held during the Fifth World Congress on Bioethics and reported that it will host the second international congress on bioethics and the development of human conscience from 22 to 25 November 2000. The Government took note of information provided by the Institute of Legal Studies, through the National Autonomous University of Mexico, on the work of an interdisciplinary body created in 1994 to analyse problems related to health and its linkages to the national legislative framework from a multidisciplinary perspective. According to the Institute, this body has been dealing with issues related to bio-technical developments and, since 1996, the human genome in particular. The Institute noted the fact that research on the human genome may produce sensitive information that could be used in ways which threaten the dignity and integrity of the human being. It further noted that several recent seminars have taken place on issues related to the human genome, with participation by various international experts. The Government indicated that there is a clear need for broad national legislative reform with regard to research on the human genome. It stressed that in reforming the national legislative framework, respect for human dignity must be taken into account with respect to the management of genetic information. The Government also noted the need to establish a multidisciplinary consultative body to provide advice on issues related to genetic research. It stressed the need for education at all levels on scientific developments, including the potential implications of advances in genomic technology for humanity and for future generations.

Finally, the Government emphasized the importance of establishing a national consultative committee made up of experts on rights and health and/or bioethics to provide direction to legislators, as well as judicial committees and government authorities, on issues arising from the management of human and animal genetic technology.

13. The Government of the Netherlands reported that a Health Council has been established to advise on issues stemming from scientific developments, including medical-ethical and legal matters, based on recommendations it receives from a medical-ethical discussion group. With regard to clinical trials, the Government noted that the Act on Medical Research Involving Human Subjects has established a practice of testing research protocols. Where research involves issues in which expertise is rare, such as gene therapy, the Central Committee on Medical Research assumes responsibility. The Government indicated that the Health Council maintains regular contact with its counterparts in other countries.

14. The Government of Pakistan provided information on the composition of the National Bioethics Committee of Pakistan, which includes the Secretary, Ministry of Science and Technology, as Chairman and the Joint Scientific Adviser, Ministry of Science and Technology, as secretary/member. The Committee includes the following members: four working scientists in the field of genetic engineering, one representative from the Ministry of Health, one representative from the Ministry of Education, one representative from the Ministry of Agriculture, one attorney familiar with human rights principles (or) a nominee of the National Human Rights Society, one representative from a non-governmental organization working in the field of bio-engineering/bio-technology, and one religious (Muslim) scholar.

15. With its reply, the Government of Peru submitted a paper prepared by the Peruvian representative to the International Bioethics Committee of UNESCO on human rights and bioethics. The paper suggests the need for new legal protection for human rights in light of recent developments in biotechnology and social change. In particular, it notes the need to safeguard certain rights related to the human genome including the right to genetic integrity, the right to know one's biological origins and reproductive rights. With regard to the establishment of national committees to assess the ethical, social and human questions raised by the biomedical research on human beings, it reports the existence of two committees associated with the Medical College of Peru: the Ethical and Deontological Review Committee of Regional Council III, which is responsible for the area including Lima, and the National Council's Ethical Review Committee. These bodies are responsible for elaborating principles of medical ethics for the country and regulating issues such as ethical conduct in doctor-patient relations and biomedical and biological research. The idea of establishing a national bioethics committee to promote the principles contained in the Universal Declaration on the Human Genome and Human Rights was also considered. The principle objectives of the committee would be to promote the protection and respect of the dignity, liberty, identity and integrity of humans in biomedical investigations. The structure and composition of the proposed committee should be multidisciplinary in nature to allow for broad discussions with a view to making concrete decisions and proposals for action. The bioethics committee should serve to channel - not restrict - biotechnical advances with a view to maximizing the contribution of these advances for the benefit of mankind.

16. The Government of Qatar indicated its support for the invitation to Governments to establish independent ethics committees to consider and evaluate the moral, social and humanitarian issues that will be raised by biomedical research and the exchange of experience with the Bioethics Committee of UNESCO. It suggested that such a committee should include specialists in jurisprudence and Sharia science, psychology, social science, biology, medico-genetic science, laboratory science and criminal law.

17. The Government of the United Kingdom of Great Britain and Northern Ireland reported the establishment of the Human Genetics Commission (HGC), which has taken over the work previously done by the Human Genetics Advisory Commission and Advisory Committee on Genetic Testing. The HGC is the advisory body on how new developments in human genetics will impact on people and on health care. Its remit is to give ministers strategic advice on the issue of human genetics, with a particular focus on social and ethical issues. Its terms of reference are as follows: to analyse current and potential developments in human genetics and to advise ministers on the likely impact of these developments on human health and health care and their social, ethical, legal and economic implications; to advise on strategic priorities in the delivery of genetic services by the National Health Service; to advise on strategic priorities for research; to develop and implement a strategy to involve and consult the public and other stakeholders, encourage public debate on the development and use of human genetic technologies and advise on ways of increasing public knowledge and understanding; to coordinate and exchange information with relevant bodies in order to identify and advise on the effectiveness of existing guidance and of the regulatory and advisory framework as a whole and consider the lessons learned from individual cases requiring regulatory decision to build up a broader picture; to consider specific issues related to human genetics and related technologies as requested by ministers; to operate in accordance with best practices for public bodies with regard to openness, transparency, accessibility, timeliness and exchange of information. The HGC will adopt a United Kingdom perspective which will take account of legal and other differences between England, Scotland, Wales and Northern Ireland, and of the status of devolved and non-devolved matters. The main priority of the HGC's work plan is to consider the storage, protection and use of genetic information, including the establishment of a set of principles. The HGC will work with other bodies in the regulatory and advisory framework for human genetics. All research on human beings or their records must be approved by independent, multidisciplinary research ethics committees, which were made a requirement by the Government in 1991. The Government is at present consulting on a framework for research governance with the aim of ensuring that the highest standards of research practice are met.

18. The Government of the United States of America reported on the work of the National Bioethics Advisory Commission. The role of the Commission is to identify principles to govern the ethical conduct of research and provide advice and recommendations to the National Science and Technology Council and other entities on bioethical issues arising from research on human biology and behaviour. The Commission does not review individual projects; rather, it considers the appropriateness of governmental programmes, policies, assignments, missions, guidelines and regulations as they relate to bioethical issues regarding research on human biology and behaviour and its applications. The Commission may accept suggestions from Congress and from the public and may conduct inquiries, hold hearings and establish subcommittees as

necessary. It considers, as a matter of priority, the protection of the rights and welfare of human research subjects and issues in the management and use of genetics information, including human gene patenting. The Commission is composed of a maximum of 18 members appointed by the President as non-Government experts and community representatives with special qualifications and competence to deal effectively with bioethical issues. It includes one member with expertise in philosophy/theology, one in social/behavioural science, one in law, one in biological research and one in medicine or an allied health profession. Membership includes at least three members selected from the general public and is to be evenly balanced between scientists and non-scientists, with due consideration to geographic distribution and ethnic and gender-balanced representation.